PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

REC'D 16 JAN 2001
WIPO PCT

Applicant's or agent's file reference PF-0627 PCT	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/US99/25458	International filing date *(day/month/year)* 28 OCTOBER 1999	Priority date *(day/month/year)* 28 OCTOBER 1998
International Patent Classification (IPC) or national classification and IPC Please See Supplemental Sheet.		
Applicant INCYTE PHARMACEUTICALS, INC.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets.

   ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 9 sheets.

3. This report contains indications relating to the following items:

   I ☒ Basis of the report

   II ☐ Priority

   III ☒ Non-establishment of report with regard to novelty, inventive step or industrial applicability

   IV ☐ Lack of unity of invention

   V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

   VI ☐ Certain documents cited

   VII ☐ Certain defects in the international application

   VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
17 MAY 2000	02 JANUARY 2001
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer PREMA MERTZ Telephone No. (703) 308-0196

Form PCT/IPEA/409 (cover sheet) (July 1998)★

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US99/25458

I. Basis of the report

1. With regard to the **elements** of the international application:*

[X] the international application as originally filed

[X] the description:
pages 1-61 , as originally filed
pages NONE , filed with the demand
pages NONE , filed with the letter of _____

[X] the claims:
pages 62-63 , as originally filed
pages NONE , as amended (together with any statement) under Article 19
pages NONE , filed with the demand
pages NONE , filed with the letter of _____

[X] the drawings:
pages 1-5 , as originally filed
pages NONE , filed with the demand
pages NONE , filed with the letter of _____

[X] the sequence listing part of the description:
pages 1-10 , as originally filed
pages NONE , filed with the demand
pages NONE , filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

[ ] the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

[ ] the language of publication of the international application (under Rule 48.3(b)).

[ ] the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

[X] contained in the international application in printed form.

[X] filed together with the international application in computer readable form.

[ ] furnished subsequently to this Authority in written form.

[ ] furnished subsequently to this Authority in computer readable form.

[ ] The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

[ ] The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. [X] The amendments have resulted in the cancellation of:

[X] the description, pages NONE

[X] the claims, Nos. NONE

[X] the drawings, sheets/~~fig~~ NONE

5. [ ] This report has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

** Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

***Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
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III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been and will not be examined in respect of:

☐ the entire international application.

☒ claims Nos. 17-18, 20

because:

☐ the said international application, or the said claim Nos. _ relate to the following subject matter which does not require international preliminary examination *(specify)*.

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. _ are so unclear that no meaningful opinion could be formed *(specify)*.

☐ the claims, or said claims Nos. _ are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 17-18, 20 .

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

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V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. statement

Novelty (N)	Claims	7-8, 14-16, 19	YES
	Claims	1-6, 9-13	NO
Inventive Step (IS)	Claims	19	YES
	Claims	1-16	NO
Industrial Applicability (IA)	Claims	1-16, 19	YES
	Claims	NONE	NO

2. citations and explanations (Rule 70.7)

Claims 1-6, 9-13 lack novelty under PCT Article 33(2) as being anticipated by Marra et al.

Marra et al. disclose a mouse cDNA. Therefore, a fragment of the polynucleotide of the reference, would potentially be a single nucleotide. The cDNA of the reference would hybridize to the polynucleotide of SEQ ID NO: 5-8 in the absence of specific hybridization conditions recited. A fragment of the cDNA of the reference would potentially be any nucleotide capable of selectively hybridizing to the polynucleotide of SEQ ID NO:5-8 described in the instant application. Therefore, the cDNA sequence disclosed in the Marra et al. reference meets the limitations of a polynucleotide molecule encoding a fragment of SEQ ID NO:1-4.

Claims 1-6, 9-13 lack novelty under PCT Article 33(2) as being anticipated by Soares.

Soares disclose a rat DNA. Therefore, a fragment of the polynucleotide of the reference, would potentially be a single nucleotide. The DNA of the reference would hybridize to the polynucleotide of SEQ ID NO: 5-8 in the absence of specific hybridization conditions recited. A fragment of the DNA of the reference would potentially be any nucleotide capable of selectively hybridizing to the polynucleotide of SEQ ID NO:5-8 described in the instant application. Therefore, the DNA sequence disclosed in the Soares reference meets the limitations of a polynucleotide molecule encoding a fragment of SEQ ID NO:1-4.

Claims 7-8, 14-16 lack an inventive step under PCT Article 33(3) as being obvious over Marra et al.

The teachings of Marra et al have been set forth above. However, Marra fails to teach a method of producing a polypeptide encoded by the cDNA, an antibody to the polypeptide produced and a method for detecting a polynucleotide in a sample using the claimed polynucleotide.

It would have been obvious to one of skill in the art, at the time of the instant invention, to have incorporated the DNA identified by Marra, into an expression vector and host cell to facilitate the production and characterization of the protein

(Continued on Supplemental Sheet.)

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

CLASSIFICATION:

The International Patent Classification (IPC) and/or the National classification are as listed below:
IPC(7): A61K 38/17, 38/19; C12N 5/10, 15/12, 15/19, 15/63, 15/64; C07K 14/47, 14/52, 16/18, 16/24 and US Cl.: 530/350, 351, 387.1, 387.9, 388.1, 388.23; 536/23.1, 23.5, 24.3, 24.31; 435/6, 69.1, 69.5, 71.1, 71.2, 471, 325, 252.3, 254.11, 320.1; 514/2, 8, 12, 885; 424/85.1

V. 2. REASONED STATEMENTS - CITATIONS AND EXPLANATIONS (Continued):
encoded thereby by employing those methods that were old and well known in the art of molecular biology at the time that the instant invention was made. Furthermore, it would have been obvious to produce antibodies to the protein, to study the localization of the protein in the cell. It would also have been obvious to one of skill in the art, at the time of the instant invention, to use the claimed polynucleotide as a probe for the detection of related polynucleotides.

Claims 7-8, 14-16 lack an inventive step under PCT Article 33(3) as being obvious over Soares.

The teachings of Soares have been set forth above. However, M\Soares fails to teach a method of producing a polypeptide encoded by the cDNA, an antibody to the polypeptide produced and a method for detecting a polynucleotide in a sample using the claimed polynucleotide.

It would have been obvious to one of skill in the art, at the time of the instant invention, to have incorporated the DNA identified by Soares, into an expression vector and host cell to facilitate the production and characterization of the protein encoded thereby by employing those methods that were old and well known in the art of molecular biology at the time that the instant invention was made. Furthermore, it would have been obvious to produce antibodies to the protein, to study the localization of the protein in the cell. It would also have been obvious to one of skill in the art, at the time of the instant invention, to use the claimed polynucleotide as a probe for the detection of related polynucleotides.

Claims 1-16, meet the criteria set out in PCT Article 33(4), because the polynucleotide, polypeptide and methods of the instant invention are important in medicine.

Claim 19 meets the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest a method for treating or preventing a disorder associated with decreased expression or activity of GFRP, the method comprising administering to a subject a polypeptide comprising an amino acid sequence selected from the group consisting of SEQ ID NO:1-4.

---------- NEW CITATIONS ----------
NONE